Innovating and digitalising mRNA vaccine and therapeutics production processes

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The RNA platform technology has emerged as one of the most promising and strategic technologies for rapid global vaccination, infectious disease control, biotherapeutics development, and preparedness for future healthcare challenges. Since this is a platform technology, the manufacturing infrastructure, the product and process analytical technologies, the product-process interactions, and learnings can be re-used or transferred from existing products to new products. To reach the full potential of this disease agnostic RNA platform, we are developing a set of synergistic technologies consisting of physical production processes (enzymatic RNA synthesis, downstream purification, and lipid nanoparticle formulation), analytical technologies, computer models and software. These technologies are co-developed under a patient-centric Quality by Digital Design (QbDD) framework. In this QbDD framework, first-principle or data-driven relationships are established between the critical process parameters (CPPs) of the production process and the critical quality attributes (CQAs) of the RNA vaccine and therapeutic product. The obtained models can be used for defining the design space and for advanced automation using model-predictive control. By combining the QbDD framework with the RNA platform, vaccines and therapeutics can be developed and mass-produced faster against a wide range of diseases. However, to accelerate the development and manufacturing of RNA products, regulatory approval of the digital tools used for process and product quality control is required. A form of “pre-qualification” or “pre-approval” could expedite development and regulatory approval by re-using and computationally processing disease agnostic-prior knowledge, based on the platform nature of both the RNA vaccine manufacturing process and of the QbDD framework.